EPA Reg. No. 2517-155



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 20, 2015

Kelly R. Hoskins Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 68138

Subject: Notice of Extension of Conditional Registration until May 17, 2017

Product Name: Sergeant's Fipronil Multi-Dose for Cats

EPA Registration Number: 2517-155 Application Date: May 4, 2015 Decision Number: 504119

Dear Mr. Hoskins:

This letter is in reference to your request to extend the conditional, time-limited registration for the above-referenced registration. The above-referenced registration contains conditions calling for the registration to expire after two years. Additionally, your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information for the above-referenced registration.

The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is therefore is granting the request to extend the two-year time-limited registration restriction. As such, the following change is being made to the terms and conditions for the product listed above:

• The two-year time-limited registration restriction has been extended. The new expiration date for the registration listed above is May 17, 2017.

Please note that the product is still subject to all other previously required conditions of registration. If your company wishes to remove the time limitations altogether, please submit to the Product Manager an amendment application for the product to change the terms and conditions of the registration. Please include with your submission a written rationale for the removal of the time limitation. As you remember, the Agency included this time limitation as a condition of registration for your product to allow for the post-market surveillance of the product. Therefore, we recommend that you include in your rationale the following information, along with any additional information or analyses you think would be helpful to the Agency (e.g., tables, charts, information on stewardship activities, etc.):

• A summary and analysis of the incidents received associated with the product, including information on the following:

http://www.epa.gov/pesticides/health/spot-on-meetings.html

Page 2 of 2 EPA Reg. No. 2517-155 Decision No. 504119

- o A comprehensive analysis of incident rates per doses distributed;
- An analysis of historical incident trends since the products' release into the marketplace;
- o An analysis of historical incident trends by weight range of animal, breed, weight range of product, etc...
- If the product is also registered in the European Union or Canada, information on incident rates per doses distributed and trends in those countries.

Please also note that requests to remove the expiration date condition are not subject to PRIA fees and do not have to be submitted under PRIA. However, these would also not be considered 90-day fast-track submissions, as the Agency requires time to fully evaluate the information provided. After receiving these submissions, the Agency will consider the incidents received since the initial registration; review the information and rationale provided; and make a decision on the request.

If you have any questions, please contact me by phone at (703) 306-0415, or via email at davis.kable@epa.gov.

Sincerely,

Kable Bo Davis, Product Manager 3 Invertebrate and Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs



10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

May 1, 2015

Kable Bo Davis, PM 3
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject:

Response to EPA Notices of Registration for

Sergeant's Fipronil Multi-Dose for Cats, EPA Reg. No. 2517-155 Sergeant's Fipronil Multi-Dose for Dogs, EPA Reg. No. 2517-156

Dear Mr. Davis:

Sergeant's Pet Care Products, Inc. (EPA Company Number 2517) is submitting a response to EPA's Notices of Registration dated May 17, 2013 for the following product registrations:

- Sergeant's Fipronil Multi-Dose for Cats, EPA Reg. No. 2517-155
- Sergeant's Fipronil Multi-Dose for Dogs, EPA Reg. No. 2517-156

Sergeant's is requesting a two year extension to the registration expiration and confirmation for each subject product. Please see enclosed Applications for Pesticide – Other (EPA form 8570-1).

Sergeant's is responding to the following condition of registration:

"You must provide the Agency with a projected 'release for shipment date' within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected 'release for shipment date' until an actual shipment date is provided in writing."

Please note that Sergeant's submitted a Response to EPA Notice of Registration for both products previously on January 10, 2014. At that time, Sergeant's had not yet begun to market these products and there was no scheduled date of release for shipment. This continues to be so, and Sergeant's will notify the Agency of a projected release for shipment date prior to marketing these products.

The Notices of Registration indicated that these registrations are time-limited and expire two years from the date the products are first released for shipment. Please consider this letter as a request to extend the registrations for another two years as well as confirmation for the revised expiration dates.

If you have any questions, please contact me at 402-938-7079 or khoskins@sergeants.com.

Sincerely,

Kelly R. Hoskins

Manager of Regulatory Affairs

West Hochen

Encl.

Please read instructions on	reverse befor	leting form.		Fo	rm Approve	ed. (2070-0060). Approval expires 05-31-98
EPA	Environmental	ed States Protection on, DC 20460	ı Agend	şy			tration dment	OPP Identifier Number
		Applicatio	n for P	esticide - S	Section	Ī		
Company/Product Number 2517-155				2. EPA Prod Kable Bo		er	3.	Proposed Classification
4. Company/Product (Name	:)			PM# 3				None Restricted
Sergeant's Pet Care Products, Cats	Inc./Sergeant's Fipro	nil Multi-Dose	For					
5. Name and Address of Appl	icant (Include ZIP Cod	le)				In accordance tical in compe		RA Section 3(c)(3)(b)(l), my
Sergeant's Pet Care Products,	Inc.			product is sir	mar or ider	nicai in comp	osition and	labeling to.
10077 South 134th Street Omaha, NE 68138				EPA Reg. No) .			
Omana, NE 00130				Product Nam				
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Amendment - Explain bel							to Agency i	letter dated XX-XX-XX
Resubmission in respons	e to Agency letter date	ed XX-XX-XX		"Me To	o" Applicat	ion		
Notification - Explain belo	ow.			Other -	Explain bel	ow.		
Explanation: Use additional paragraphs Sergeant's is requesting Registration. Please see	a two year extens	sion to the re	d Section egistratio	II.) n expiration	and con	firmation in	respons	e to the Notice of
			Sect	ion III				
Material This Product Will E	3e Packaged In:							
Child-Resistant Packaging	Unit Packaging		Water	Soluble Packa	aging	2. Ty	pe of Conta	ainer
Yes*	Yes		-	Yes		-	Metal	
L No	If "Yes"	No. per	If "Yes	No No	No. per	 	_ Plastic	
*Certification must	Unit Packaging wgt.	Container		ge wgt.	Containe	er	Glass	
be submitted	1				I	-	Paper	pecify) Plastic Bag
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						On La	abeling acc	companying product
6. Manner in Which Label is A	Affixed to Product	Lithogra	ph	Other				
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Contact Point (Complete its	ems directly below for	Title		i to be contacte	ea, ii rieces	ssary, to proce		ne No. (Include Area Code)
Name Kelly R.	Hoskins			gulatory Affai	rs		l (ciopiio)	402-938-7079
I certify that the statemer acknowledge that any knowledge that the statement of th	nts I have made on this	Certifica s form and all a ading statemen	attachment	ts thereto are to	rue, accura ine or impri	ite and comple isonment or b	ete. I oth	6. Date Application Received (Stamped)
2. Signature		3	. Title					
BY:	7 *** ·			Manager	of Regulate	ory Affairs		
4. Typed Name: Kelly F	R. Hoskins	5	. Date:	May 4, 2015				



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 17, 2015

Mr. Kelly R. Hoskins Director of Regulatory Affairs Sergeant's Pet Care Products, Inc. 10077 South 134th Street Omaha, NE 681388-3710

Subject: Condition of Registration – Storage Stability and Corrosion Characteristics Data

Product Name: Sergeant's Fipronil Multi-Dose for Cats

EPA Registration Number: 2517-155 Application Date: May 15, 2015 Decision Number: 505170

Dear Mr. Hoskins:

The Agency has reviewed the study cited to fulfill the conditional data requirement referred to above, in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act. Your request to cite MRID 48999601 in support of this registration is acceptable. The condition of registration is considered fulfilled.

If you have any questions, you may contact Julie Chao at (703) 308-8735 or via email at chao.julie@epa.gov.

Sincerely,

Kable Bo Davis, Product Manager 03 Invertebrate & Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

Plug Sum De for

Enclosure



10077 South 134th Street • Omaha, NE 68138- 3710 • Telephone 402.938.7000 • Fax 402.938.7091 • www.sergeants.com

May 15, 2015

Kable (Bo) Davis, PM3
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

4 115

Subject:

Sergeant's Fipronil Multi-Dose for Cats (EPA Reg. No. 2517-155)

Storage Stability and Corrosion Characteristics (OCSPP 830.6317 and OCSPP

830.6320) Data

Dear Mr. Davis:

Sergeant's Pet Care Products, Inc. (Sergeant's, 10077 South 134th Street, Omaha, NE 68138-3710, EPA Company Number 2517) is responding to the EPA's Notice of Registration dated May 17, 2013 for Sergeant's Fipronil Multi-Dose for Cats to address some of the conditions of registration.

At this time, Sergeant's has not determined a release for shipment date for this product. Prior to releasing the product for shipment, Sergeant's will notify the Agency in writing, and will provide a copy of the final printed label.

Sergeant's is also submitting a response to address the Storage Stability (OCSPP 830.6317) and Corrosion Characteristics (OCSPP 830.6320) data requirements.

For the reasons discussed in the Confidential Attachment, Sergeant's is citing the MRID 48999601 to address the conditional data requirements: Storage Stability and Corrosion Characteristics (OCSPP 830.6317 and OCSPP 830.6320) (MRID 48999601). Please see the enclosed copy of the updated data matrix listing the above-referenced data.

This Confidential Attachment contains CONFIDENTIAL BUSINESS INFORMATION and must not be released to any third party.

If you have any questions regarding this submission, please contact me at 402-938-7079.

Sincerely,

Kelly R. Hoskins Director of Regulatory Affairs

Enclosures

Please read instructions on rev	verse before pletin	g form.	Form Approve	ed. \ 40. 2	070-0060. A	pproval expires 05-31-98
	United Sta	ates		Regist	ration	OPP Identifier Number
EPA En	nvironmental Prof		ncv	Amend	1	
	Washington, D	•	iloy			
		lication for	Pesticide - Section			
Company/Product Num	nber		2. EPA Product	Manager	3. Pro	posed Classification
2517-155 4. Company/Product (Name)			Kable (Bo) Davis		-	
Sergeant's Fipronil Multi-Dose I	For Cats		5. PM #3			NoneRestricted
5. Name and Address of Applica	int (Include ZIP Code)		Expedited Review. product is similar or ider			
Sergeant's Pet Care Products, Inc	.c.		1	ilicai iii compos	sition and labe	anny to.
10077 South 134th Street			EPA Reg. No.			
Omaha, NE 68138			Product Name			
Check if this is	a new address					
		S	ection II			
Amendment - Explain below			Final printed labels	in response to	Agency letter	r dated XX-XX-XX
		, ,,,,,,,,	15	-		
Resubmission in response to	o Agency letter dated XX	(-XX-XX	"Me Too" Applicat	ion		
Notification - Explain below.			Other - Explain bel	ow.		
Explanation: Use additional pag	ge(s) if necessary. (For s	section I and Sec	ction II.)			
Citation of 12 month Storage S Dose For Cats (EPA Reg. No. 2		Characteristics	(OPPTS 830.6317 and OPP	TS 830.6320) d	lata for Serge	eant's Fipronil Multi-
		S	ection III			
Material This Product Will Be I	Packaged In:					
	Jnit Packaging		Water Soluble Packaging	2. Type	e of Containe	r
Yes*	Yes		Yes		Metal	
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ZZrapeiCO	Titalilei 3.30		43 H 02. (230 HII)			panying product
6. Manner in Which Label is Affix	xed to Product	Lithograph	Other			
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		S	ection IV			
Contact Point (Complete item.	is directly below for ident	ification of indivi	dual to be contacted, if neces	sary, to process	s this applicat	ion.)
Name		Title			•	lo. (Include Area Code)
Kelly R. Ho	oskins		Director of Regulatory Affai	rs		102-938-7079
		Certification				6. Cate Application Received
I certify that the statements acknowledge that any know under applicable law.	I have made on this form ringly false or misleading	n and all attachm statement may	nents thereto are true, accura be punishable by fine or impr	te and complete isonment or bot	e. I th 	(Stamped)
2. Signature		3. Title				1
	Her Zitieres	,	Director of Regulate	ory Affairs		
4. Typed Name: Kelly R. I		5. Date:	5/15/2015]

Page 9 - *Claimed confidential by submitter*

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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	DATA MATRIX				
Date: May 15, 2015		EPA Reg No./File S	ymbol 2517-155	F	Page 1 of 4
Applicant's/Registrant's Name &		Product: Sergeant's	Fipronil Multi-Dose for C	ats	
	. 10077 South 134th Street, Omaha, NE 68138-3710				
Ingredients: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	
830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1700, 830.1750	Product Properties Data for Sergeant's Fipronil Squeeze-On for Cats	48059501	Sergeant's Pet Care Products, Inc.	OWN	
830.1800	Enforcement analytical method	48122601	Sergeant's Pct Care Products, Inc.	OWN	
830.6302, 830.6303, 830.6304, 830.7300, 830.7000, 830.6315, 830.7100, 830.6320, 830.6317	Product chemistry of Sergeant's Fipronil Squeeze-On for Cats	48059502	Sergeant's Pet Care Products, Inc.	OWN	
830.6317, 830.6320	Storage stability and corrosion characteristics	48999601	Sergeant's Pet Care Products, Inc.	OWN	
870.1100	Acute oral toxicity	43577705	MERIAL LIMITED	OLD	
870.1200	Acute dermal toxicity	43577706	MERIAL LIMITED	OLD	
870.1300	Acute inhalation toxicity	43577707	MERIAL LIMITED	OLD	
870.1400	Primary eye irritation	43577708	MERIAL LIMITED	OLD	
870.1500	Primary dermal irritation	43577709	MERIAL LIMITED	OLD	
870.1600	Dermal sensitization	43577710	MERIAL LIMITED	OLD	
870.7200	Arnaud, J.: Consalvi, P. (1993) Domestic Animal Safety: Assessment of the Tolerance of a 0.25% RM 1601 Spray Formulation in Cats at 3, 9, and 15 ml/kg When Applied 6 Times to the Haircoat at 28 Day Intervals: Revised: Lab Project Number: CLI 137. Unpublished study prepared by Rhone Merieux, Inc. 62 p.	43121112	MERIAL LIMITED	OLD	
870.7200	Schwartz. E. (1994) Domestic Animal Safety Study of RM1601C 0.25% Topical Spray in Juvenile Cats: Interim Report: Lab Project Number: 94424. Unpublished study prepared by White Eagle Toxicology Lab. 112 p.	43272401	MERIAL LIMITED	OLD	
870.7200	Schwartz, E. (1994) Domestic Animal Safety Study of RM1601C Topical Spray (Frontline Spray Treatment) in Juvenile Cats: Lab Project Number: 94424: PS-234DAS. Unpublished study prepared by White Eagle Toxicology Labs. 168 p.	43444904	MERIAL LIMITED	OLD	
Signature.		Name and Title Kelly R. Hoskins, Di	rector of Regulatory Affa	irs	Date 5/15/201:

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	DATA MATRIX				
Date: May 15, 2015		EPA Reg No./File			ige 2 of 4
Applicant's/Registrant			Fipronil Multi-Dose for		
	oducts, Inc. 10077 South 134th Street, Omaha, NE 68138-3710	Cats			
Ingredients: Fipronil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7200	Walker, K. (1995) Discussion in Support of Bridging Domestic Animal Safety Data on Frontline Spray Treatment to Frontline Spot Treatment Data Package. Unpublished study prepared by Rhone Merieux, Inc. 6 p.	43577711	MERIAL LIMITED	OLD	
870.7200			MERIAL LIMITED	OLD	
870.7200 Cameron, D.; Maltby, B. (1995) Domestic Animal Safety by Topical Administration to Cats: Fipronil Spot Treatment: Lab Project Number: MRX 24/950746. Unpublished study prepared by Huntingdon Research Centre, Ltd. 174 p.			MERIAL LIMITED	OLD	
870.7200	Clery, D. (1999) Fipronil/(S) – Methoprene/Topical/Solution/Target Species Safety Study in the Cat: Interim Final Report: Lab Project Number: GB011/99 – 001: PR&D 0023301. Unpublished study prepared by Biological Labs. Europe Ltd. 127 p.	44942009	MERIAL LIMITED	PAY	
870.7200			MERIAL LIMITED	PAY	
810.3300			MERIAL LIMITED	PAY	
810.3300	Everett, R.: Cunningham, J. (1993) A Dose Titration Study to Determine the Optimal Spray Concentration of RM1601 for Long Term Control of the Cat Flea Ctenocephalides felis and Brown Dog Tick Rhipicephalus sanguineus in the Dog: revised: Lab Project Number: RM 292: P/214LT. Unpublished study prepared by Agresearch Consultants. 53 p.	D	MERIAL LIMITED	OLD	
810.3300	Cruthers, L. (1993) Product Performance: A Dose Confirmation Study to Verify the Optimal Spray Concentration of RM 1601 for Long Residual Control of the Cat Flea (Ctenocephalides felis) and the Brown Dog Tick (Rhipicephalus sanguineus in the Dog: Revised: Lab Project Number: 9251: P/215LT. Unpublished study prepared by Professional Labs and Research Services, Inc. 51 p.	3	MERIAL LIMITED	OLD	
Signature:		Name and Ti Kelly R. Hos Affairs	tle kins. Director of Regulat	ory	Date 5/15/201:

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	DATA MATRIX					
Date: May 15, 2015				ymbol 2517-155		age 3 of 4
Applicant's/Registrant	t's Name & Address oducts, Inc. 10077 South 134th Street, Omaha, NE 68138-3710	Product: Cats	Sergeant's	Fipronil Multi-Dose for		
Ingredients: Fipronil	oddets. He. 10077 Soddi 154ti Sueed Omana 702 00150 5710	Cuis				
Guideline Reference Number	Guideline Study Name		MRID Number	Submitter	Status	Note
810.3300	McCall, J.; McTier, T. (1993) Laboratory Evaluation of RM 1601 Spray for Control Dermacentor variabilis and Rhipicephalus sanguineus on the Dog: Lab Project Number: RM/TKS/93/1L; PS/229LT. Unpublished study prepared by TRS Labs. Inc. 18 p.	4	3121117	MERIAL LIMITED	OLD	
810.3300	Everett, R.: Cunningham, J. (1993) An Investigation Study to Evaluate the Effect of Bathin Laboratory Dogs on the Efficacy of RM1601 Spray: Revised: Lab Project Number: RMD 592: P/220LT. Unpublished study prepared by Agresearch Consultants, Inc. 43 p.		3121118	MERIAL LIMITED	OLD	
810.3300	Young. R. (1993) A Preliminary Study to Evaluate Initial and Residual Efficacy of Two RN 1601 Spray Formulation Topically Applied for Control of the Cat Flea in the Cat: Lab Pro Number: P-211LT. Unpublished study prepared by Young Veterinary Research. 28 p.	oject	3121119	MERIAL LIMITED	OLD	
810.3300	Cruthers, L. (1993) A Dose Confirmation Study to Verify the Optimal Spray Concentration RM1601C for Control of the Cat Flea Ctenocephalides felis in the Cat: Revised: Lab Project Number: PLRS 9303: P/224LT. Unpublished study prepared by Professional Labs and Research Services. Inc. 31 p.		3121120	MERIAL LIMITED	OLD	
810.3300	Everett, R.: Cunningham, J. (1993) Dose-Titration (Volume) of RM 1601 Spray for Control the Cat Flea Ctenocephalides felis in the Cat: Revised: Lab Project Number: RMD 393: P/228LT. Unpublished study prepared by Agresearch Consultants, Inc. 41 p.	ol of 4	3121121	MERIAL LIMITED	OLD	
810.3300	Cruthers, L. (1993) Efficacy of RM1601C at 3 ml/kg and 6 ml/kg Against Ixodes scapularis/dammini Nymphs, Dermacentor variabilis Nymphs, Amblyomma americanum Nymphs, Rhipicephalus sanguineus Nymphs, and Ctenocephalides felides Adults Using Treated Dog Hair as the Testing Substrate: Revised: Lab Project Number: 9320: P/225L/Unpublished study prepared by Professional Lab and Research Services, Inc. 28 p.		3121122	MERIAL LIMITED	OLD	
810.3300	McCall, J.; McTier, T. (1995) Positive Referenced and Untreated Controlled, Confirmatory Laboratory Trial of RM1601E SPOT-ON Formulation Applied to Dogs as 3 Weight Class Defined Volumes for the Control of the Cat Flea Ctenocephalides felis, the Brown Dog Tic Rhipicephalus sanguineus, and the American Dog Tick Dermacentor variabilis: Lab Project Numbers: RM/FLS-TKS/94/2L: RMI VSR-249LT: PT-249LT. Unpublished study preparaby TRS Labs, Inc. 41 p.	:k ct	3577712	MERIAL LIMITED	OLD	
Signature:		Ke	me and Tit lly R. Hosk fairs	le ins. Director of Regulate	ory	Date 5/15/201:
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	DATA MATRIX					
Date: May 15, 2015		EPA Reg	PA Reg No./File Symbol 2517-155			age 4 of 4
Applicant's/Registrant	t's Name & Address oducts, Inc. 10077 South 134th Street, Omaha, NE 68138-3710	Product: S Cats	Sergeant's	Fipronil Multi-Dose for		
Ingredients: Fipronil	oddets, me. 10077 Bodin 15 tal backet olitalia. (12) 00100 5 (10)	Cuts				
Guideline Reference Number	Guideline Study Name	- 1	MRID lumber	Submitter	Status	Note
810.3300	Everett, R.: Cunningham, J.: Tanner, P. (1995) Positive Referenced and Untreated Control Dose Confirmation Trial of RM1601E 10% SPOT-ON Formulation Applied to Cats for Control of the Cat Flea Ctenocephalides felis: Lab Project Numbers: RM VSR-250LT: A #RMC194: P-250LT. Unpublished study prepared by AgResearch Consultants, Inc. 30 p.	ARC	3577713	MERIAL LIMITED	OLD	
810.3300	Pollmeier, M. (1999) An Efficacy Study of Frontline Top Spot for the Treatment and Control of Felicola subrostratus in the Cat: Final Report: Lab Project Number: PR&D 0022201. Unpublished study prepared by Centro Veterinario Oriolo. 18 p.		6628101	MERIAL LIMITED	PAY	
810.3300	Pollmeier, M.; Pengo, G.; Barrick, R. (2000) An Efficacy Study of Frontline Spray, Frontli Top Spot and ML-2.095,988 508Q for the Treatment and Control of Felicola subrostratus i the Cat: Final Report: Lab Project Number: PR&D 0037201. Unpublished study prepared Centro Veterinario Oriolo. 22 p.	in	6628102	MERIAL LIMITED	PAY	
810.3300	Pollmeier, M.: Pengo, G. (2001) Studies to Confirm the Efficacy of Fipronil Against Lin Cats Under Field Conditions: Final Report: Lab Project Number: PR&D 0037501. Unpublished study prepared by Centro Veterinario Oriolo. 20 p.	ice 45	628103	MERIAL LIMITED	PAY	
Signature:			•	e ins. Director of Regulate	ory	Date 5/15/201

Material Sent for Data Extraction

Reg. #
Description:
Material(s) Sent to Data Extraction Contractors:
New Stamped Label Dated 5-17-13
Notification Dated
New CSF(s) Dated 4-2y-12
Other:
☐ Decision #: 470501
Other Action/Comments:
File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the acket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.
Reviewer: Carmen Rodia
Phone: (703) 306-0327 Division: RD/IB
Date: >-17-3

ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7504P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460-0001 EPA Registration No.

2517-155

Date of Issuance:

May 17, 2013

NOTICE OF PESTICIDE:

☑ Registration

☐ Reregistration

(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Sergeant's Fipronil Multi-Dose for Cats

Name and Address of Registrant (include ZIP Code):

Sergeant's Pet Care Products, Inc. 10077 South 143th Street Omaha, NE 68138-3710

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This action is taken under the authority of section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

Terms of Registration

- 1. EPA has registered the product listed above provided that the following changes are made to the label before you release the product for shipment:
 - a. Revise the EPA Registration Number to read: "EPA Registration No 2517-155."
- 2. This registration is time-limited and expires two years (2) from the date this product is first released for shipment. You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.
- Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient).
- 4. You must submit the following data within the timeframe described below: Within sixteen (16) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).

Signature of Approving Official:

Date:

Refer to Page #3

May 17, 2013

Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch

EPA Form 8570-6

You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on July 1, 2013. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division (attn: Kaitlin Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number

Product name (brand name)

Lot#

Where purchased: internet, store, Veterinarian

Active Ingredient(s)
Weight range for product

Date on which incident occurred, (mm/dd/yyyy)

State in which the incident occurred, (standard 2 letter abbreviation)

Registrant case #

Species: dog, cat, other (specify) Breed: (as reported by pet owner)

Age: months or years Sex: M. F, or neutered Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other

Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted

Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no

Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)

Any known precondition

EPA Severity Code: death, major, moderate, minor

Outcome: died, recovered, still treated, unknown

- Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
 - a. All minor dermal and ocular irritation reports.
 - b. Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - c. A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for dogs and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - e. A summary table for s showing number of incidents for each severity code for these age ranges: <3 months. 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - g. A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
 - h. Table showing number of incidents for each dog breed.
 - i. Table showing number of incidents in dog for each clinical sign.
 - j. Table showing number of incidents in dog for each organ system.
 - k. Report aggregate incidents, but do not combine moderate and minor incidents.
- 3. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.

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- 4. Sergeant's Pet Care Products. Inc. must adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot-On Mitigation Plan* available at the following internet site: http://www.epa.gov/pesticides/health/spot-on-meetings.html.
- 5. Enclosed is a copy of the data call-in (DCI) for fipronil.

You must submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact Mr. Richard J. Gebken at (703) 305-6701 or gebken.richard@epa.gov.

Sincerely

Richard Gebken Product Manager 10 Insecticide Branch

Registration Division (7504P)

I Car (

Enclosures:

Label Stamped "Accepted with Comments," dated May 17, 2013

Copy of DCI for Fipronil

002517-00155 D470265

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Information in [] is optional.

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Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels.]

Sergeant's Fipronil Multi-Dose for Cats

[ABNs:]

[Sergeant's® EctoadvanceTM Spot On for Cats]

[Sergeant's® EctoadvanceTM for Cats]

[Sentry® EctoadvanceTM Spot On for Cats] [Sentry® EctoadvanceTM for Cats]

[Meridian® EctoadvanceTM Spot On for Cats]

[Meridian® EctoadvanceTM for Cats]

May 17, 2013 Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the

pesticide registered under:

2517-155 EPA. Reg. No:

FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels. Not for residential use. Keep product in its original container. Do not repackage.

[For use ONLY on cats [[&] [and] kittens] over 1.5 lbs. and over 8 weeks of age] [Only for cats [[&] [and] kittens] over 8 weeks of age and over 1.5 lbs.]

[Ideal for shelter use when under direct supervision of veterinarian]

[Multi-dose bottle] [Multi-Dose Package]

[Convenient multi-dose bottle for in clinic use]

[Convenient multi-dose bottle for animal facility use]

[Accurate and convenient dosing for all sizes of cats]

[For use only by licensed veterinarians [on animals in their control or under their immediate supervision]

[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 14 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]

[Fleas]

[Kills adult fleas [for up to six weeks]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If cat is a high risk for flea reinfestation apply once a month]

[Kills fleas which may be a source of flea allergy dermatitis] [and] [flea bite anemia]]

[Ticks]

[Kills ticks including those that may transmit Lyme disease]

[Kills deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]

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[Kills ticks [including][brown dog ticks] [(Rhipicephalus sanguineus)] [American dog ticks,] [(Dermacentor variabilis)] [and] [lone star ticks] [,][and] [deer ticks] [for up to [4 weeks] [1 month] [30 days]]]

[Multiple Infestations]

[Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old and older]

[Kills fleas, ticks, [mosquitoes] [&] [and] chewing lice]

[Monthly flea, tick, [mosquito] and chewing lice protection]

[Four] [4] [Three] [3] Way [Action] [Effectiveness] [Control] [kills fleas, [mosquitoes,] ticks, and chewing lice]

[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]

[[Four (4) Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]

[Once A Month Flea and Tick Treatment]

[Use [Brand Name] monthly to control ticks and chewing lice]

[Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]

[(**Brand Name**) provides convenient and effective flea, tick, chewing lice [and] [mosquito] control for cats and kittens over 8 weeks of age.]

[All Others]

[For Cats and Kittens 8 weeks of age or older]

[Can [use][apply] [on][to] kittens 8 weeks of age and older]

[Specially Formulated for Cats and Kittens Over 8 Weeks Old]

[Easy to Use [Application]]

[Apply monthly]

[Apply once every [4 weeks] [month] [30 days]!]

[Waterproof]

[Effective after bathing and exposure to water and sunlight]

[Can be used on breeding, pregnant and lactating [queens], [female] [cats]]

ACTIVE INGREDIENT:

[**diethylene glycol monoethyl ether]

KEEP OUT OF REACH OF CHILDREN CAUTION

[See [Back] [Label] for Additional Precautionary Statements]

Net Contents:

[3.38 fl oz [(100 ml)]] [8.45 fl oz [(250 ml)]]

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON CATS AND KITTENS OVER 8 WEEKS OF AGE

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[[Brand Name] for cats provides [[four] [three] [way] protection that kills fleas, ticks, [mosquitoes] and chewing lice. Kills deer ticks that may transmit Lyme disease. Kills brown dog ticks, American dog ticks, and lone star ticks. Prevents flea reinfestation for [[4][four] weeks] [[1] [one] month] [30 days].]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use on cats only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat a cat with more than one pesticide product at a time. Over dosing a cat can result in serious illness and even death. Use caution before using on medicated, debilitated, aged, pregnant, nursing cats, or cats with known organ dysfunction. If the cat is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

	FIRST AID				
If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.				
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.				
If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists.					
	HOTLINE NUMBER				

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND THE CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on rabbits or animals other than cats. Do not allow your cat to ingest this product. Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 1.5 lbs. Do not over dose cat. Instruct the cat owner to separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

Side Effects: Instruct the owner to monitor the cat after application. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed the cat and continue to monitor the cat for the next 24 hours. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe the cat with a mild soap and rinse with large amounts of water. If signs persist or become more severe within a few days of application, immediately call 1-800-781-4738. If the cat has an unusual reaction to the initial application, evaluate the cat's condition before repeating application.

[CRP text found on top of cap: WHILE PUSHING DOWN TURN CLOSE TIGHTLY][Graphic may or may not appear anywhere on the label]



How to Apply

Weight/Application Amount					
Only for cats and kittens 8 weeks or older and over 1.5 lbs.					
Weight:	Apply:				
All sizes (weights) (0.50 mL) or (0.50 cc)					

Application to be made using commercially available ≥1 mL (syringe must have 0.1 mL graduations), luer tip disposable syringe without needle. Use of non-sterile syringe is acceptable since applications are topical. Use syringe [(not included)] to measure and withdraw the appropriate amount of solution by inserting the syringe into the top of the bottle. Refer to table above for application rates. Part the cat's hair, and apply entire amount directly to the skin of the cat, as directed below. Do not apply more often than once every 4 weeks. When finished using product, replace the cap.

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FREQUENCY OF APPLICATION

[Brand Name] [This product] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Keep product in its original container. Do not repackage. Store in a cool (below 77°F[/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

SYRINGE DISPOSAL: Do not reuse this syringe. Only discard empty syringes; do not discard syringes containing product. Discard disposable syringe in accordance with State and Local regulations.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738

[Coupon(s) inside or on outside of box]

Non-Emergency, call: 1-800-224-PETS (7387)

[Made in USA]

Distributed by: Sergeant's Pet Care Products, Inc. Omaha, NE 68138-3710

[BAR CODE AREA][Lot code] EPA Reg. No. 2517-RLL EPA Est. No. 2517-NE-1 [XXX-XX-XXX]

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[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist

- [1] Read the label completely and follow directions
- [2] Weigh the cat
- [3] Do NOT use cat products on dogs
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals for 24 hours after treatment to avoid chance of ingestion
- [6] Not for residential use

[Optional graphics below may or may not appear anywhere on finished label]

The same of the sa	Fleas	
150/st	Adult Flea	
	Ticks	
	Deer Tick	
	Brown Dog Tick	
*	Lone Star Tick	
*	American Dog Tick	
*	Chewing Lice	
1	Mosquitoes	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (2505P)

March 11, 2013

MEMORANDUM:

Subject:

Name of Pesticide Product:

Sergeant's Fipronil Multidose for Cats

EPA Reg. No. /File Symbol: 2517-RLL

DP Barcode:

DP 407765

Decision No.: Action Code:

470265 R310

PC Code:

129121 (Fipronil: 9.7%)

From:

Byron T. Backus, Ph.D., Toxicologist

Technical Review Branch

Registration Division (7505P)

To:

Byrn T. Books March 11, 2013 MHashin TL. TOXICOLOGY Driss Benmhend/Richard Gebken RM 10

Insecticide Branch

Registration Division (7505P)

Registrant:

SERGEANT'S PET CARE PRODUCTS, INC.

FORMULATION FROM LABEL:

Active Ingredient(s):

by wt.

129121 Fipronil Other Ingredients: 9.70%

TOTAL

90.30% 100.00%

ACTION REQUESTED: "I am attaching the Toxicity data submitted by Sergeant's Pet Products to support the application to register the new end-use product Sergeant's Fipronil Multi-Dose Spot on for Cats containing the active ingredient Fipronil..."

BACKGROUND: The material received by TRB includes a cover letter (dated September 28, 2012), a basic CSF (dated 09/28/2012), a proposed label (which states that the minimum kitten/cat age is 8 weeks and that the product can be used on all weights of kittens/cats), a data matrix (dated 09/28/2012), and a letter relating to child-resistant packaging self certification which includes the following statements: "The containers to be used are bottles, which will contain 3.38 fluid ounces (100 mL) or 8.45 fluid ounces (250 mL)..." and "...this product is for use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels. It is not for residential use. This product is not for sale, distribution to or use by pet owners or home owners."

COMMENTS AND RECOMMENDATIONS:

1. According to the data matrix dated 09/28/2012 the registrant has cited 6 acute toxicity studies (MRIDs 43577705 through 43577710) to satisfy the acute toxicity data requirements for 2517-RLA. These studies have been recently rereviewed (TXR 5013861, memorandum dated 07/26/2012); previously, these studies were cited to support the registration of 65331-3. After examining information as to composition of the test material in the cited studies and the CSF for 2517-RLL, TRB concludes that these studies can be used to satisfy the acute toxicity data for 2517-RLL, which would then have the following acute toxicity profile:

Acute oral toxicity	III	Cited	MRID 43577705
Acute dermal toxicity	IV	Cited	MRID 43577706
Acute inhalation toxicity	IV	Cited	MRID 43577707
Primary eye irritation	III	Cited	MRID 43577708
Primary dermal irritation	III	Cited	MRID 43577709
Dermal sensitization	Negative	Cited	MRID 43577710

2. Based on the acute toxicity profile given above, the following is the precautionary and first aid labeling for 2517-RLL as obtained from the Label Review System:

PRODUCT ID #: 002517-00155

PRODUCT NAME: SERGEANT'S FIPRONIL MULTI-DOSE FOR CATS

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. [Wear protective eyewear.]*

^{*[}Protective eyewear may be specified, if appropriate].

First Aid:

If swallowed:

- -Call a poison control center or doctor immediately for treatment advice.
- -Have person sip a glass of water if able to swallow.
- -Do not induce vomiting unless told to by a poison control center or doctor.
- -Do not give anything to an unconscious person.

If on skin:

- -Take off contaminated clothing.
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

If in eyes:

- -Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- -Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- -Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

- 3. The companion animal safety study (870.7200) citations are MRIDs 43121112, 43272401, 43444904, 43577711, 43577716, 43863801, 44942009, and 45615802.
- 4. The study in MRID 43121112 was reviewed (TXR 0010923, HED review dated 04/19/94) with the following summary:

Groups of three male cats were topically administered six treatments of the 0.25% fipronil formulation at dosages of either 0, 3, 9 or 15 ml/kg (0, 7.5, 22.5 and 37.5 mg/kg, respectively) at 28-day intervals. (The proposed recommended dose for cats is 3-6 ml/kg.)

Food consumption was significantly decreased in the 15 ml/kg group as compared to the control group at weeks 2 and 4 after the first treatment. All other time points were comparable. The incidences of vomiting and soft/liquid feces were higher in the treated animals as compared to the controls.

Classification: Unacceptable because: 1) the highest dosage level was not at 5X the highest recommended dose; 2) only three male cats per dosage group were included in the study; and 3) the study was not conducted in compliance with the GLP regulations.

- 5. The study in MRID 43272401 was an interim report for the study that was subsequently submitted to the Agency under MRID 43444904.
- 6. The study in MRID 43444904 was reviewed (TXR 0011405; HED review dated 02/01/95) with the following summary:

Material Tested: RM1601C (0.25% fipronil); Trade Name: Frontline

In this domestic animal safety study (MRID # 434449-04), 4 male and 4 female domestic short hair kittens (≤ 8 weeks of age) were administered a single topical treatment of RM1601C (0.25% fipronil) at 6 ml/kg (recommended dosage) once every month for three months. Another group of 6 male and 6 female kittens were treated in a like manner with five times the recommended dosage. A group of 4 male and 4 female kittens served as a control group and were treated with the formulation vehicle at 5% the recommended dosage. The following parameters were evaluated: physical examinations, clinical observations, body weight, food consumption, hematology, clinical chemistry and gross necropsy examination of the abdominal cavity. There was no evidence of a treatment-related effect on any of the parameters. The study demonstrated that the RM1601C (0.25%) has at least a 5% margin of safety in kittens.

- 7. The information in MRID 43577711 was reviewed (TXR 0011764; HED review dated Jan. 24, 1996) with the following comments:
 - A. Discussion in Support of Bridging Domestic Animal Safety Data on Frontline® Spray Treatment to Frontline® Spot Treatment Data Package MRID# 43577711

The document presents an argument on why there is justification for linking the new product, Frontline® Spot Treatment (10% w/v fipronil), to the existing product's (Frontline® Spray Treatment, 0.25% w/v fipronil) domestic animal data base. The following points are included:

- No adverse toxicity to dogs and cats were observed in the efficacy studies.
- The acute toxicity studies for both formulations have been classified Category III. (Toxicology Branch II did not review these studies for the 10% formulation.)
- In the domestic animal safety studies, the 0.25% formulation was administered to adult and juvenile animals at five times the recommended dose (30 ml/kg). A comparison of the actual active ingredient applied to the animal at maximum rates illustrates that less active ingredient was applied with the 10% formulation, except for cats weighing less than 2 kg. A comparison table shows the following comparisons.

Dog Bodyweight (kg)	Spot Treatment Total Dose (mg)	Spray Treatment Total Dose (mg)
5	67	75
10	134	150
20	268	300
Cat Bodyweight (kg)	Spot Treatment Total Dose (mg)	Spray Treatment Total Dose (mg)
2	50	30
4	50	60
8	50	120

Extracted from text table on page 5.

• The inerts in the two formulations differ. However, those found in the 10% formulation are listed on the Pesticide Product Inert Ingredients List or the GRAS list. The vehicle control for this formulation was tested in an acute toxicity battery and showed the same level of toxicity as the formulation.

8. The study in MRID 43577716 was reviewed (TXR 0011764, HED review dated Jan. 24, 1996) with the following comments:

Percutaneous Absorption and Distribution of Radioactivity in Hair, Skin, and Fat After Spot-On Application of ¹⁴C-RM1601 in Cats - MRID # 43577716

Material Tested: 14C-RM1601 (96.6%)

A single dermal 50 mg dose of ¹⁴C-RM1601 (fipronil) was administered to three male European cats at a single location between the shoulder blades. Plasma levels of the radioactive chemical were determined at various time points. The animals were sacrificed at either day 7, 15 or 30, and hair, skin and fat samples from the application site and an untreated area were analyzed for radioactivity.

The study demonstrated that systemic absorption of fipronil is insignificant in cats. The highest concentration of the chemical was found in hair at Day 30 post-treatment. Skin radioactivity was only detected at the application site and was highest 15 days post-treatment. There was a good distribution of the chemical in the hair, with a gradient of treatment between the application site and the untreated area. The only radioactivity found in fat was at the application area at 30 days post-treatment.

Classification: Unacceptable. The study does not satisfy the guideline requirements for a dermal absorption study. The total dose of radioactive chemical was not accounted for in urine, feces, and carcass. Therefore, a percentage of the dermal dose absorbed systemically could not be calculated.

Although this study was classified as unacceptable it supports the label claim for EPA File Symbol 2517-RLL that the product (or perhaps the active ingredient) "collects in the oils of the skin and the hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity..."

9. The study in MRID 43863801 was reviewed (TXR 0051187, HED review dated Jan. 24, 1996) with the following comments:

Material Tested: RM1601E/62 (9.7% fipronil)

In this domestic animal safety study, 4 male and 4 female domestic short hair cats (approximately 12 weeks of age) were administered a single topical treatment of RM1601E/62 (9.7% fipronil) of either 0.25 ml/kg (1x), 3x or 5x that dose once every month for a total of six treatments. A group of 4 male and 4 female kittens served as a control group and were treated with the formulation vehicle at 5x the 1x dose. A similar group served as an untreated control. The following parameters were evaluated: clinical observations, body weight, food consumption, water consumption, hematology and clinical chemistry. As there was no ante-mortem evidence of any treatment-related effects, necropsy examinations were only of the application sites. The study was not conducted in accordance with the protocol design. The label recommended dose is 0.5 ml, regardless of the animal's weight. This dose was not achieved until the fourth treatment for most animals when they were approximately 24 weeks old. However, since three treatments at this dose were applied, Toxicology Branch II judges that the study is adequate. The study demonstrated that RM1601E/62 (9.7% fipronil) has at least a 5x margin of safety in cats greater than 24 weeks of age.

Classification: Acceptable

10. The study in MRID 44942009 was reviewed (TXR 5001487, TRB review dated April 12, 2000) with the following comments:

...Fipronil/s-Methoprene solution for cats (Active Ingredients: Fipronil:10% w/v; (S)-methoprene:12% w/v) was topically applied at dose levels of 0.5 mL (1X), 1.5 mL (3X) or 2.5 mL (5X times the maximum recommended dose) to groups of 6 male and 6 female kittens (52-59 days old at the initiation of the study). Controls were not dosed. Animals were treated on Study Day 0 and again on Study Day 28. The report includes results of the study up to Day 42...

No clinical signs of erythema, edema, alopecia or abnormal hair coat condition were observed 1-6 hr post-dosing in any of the treated animals or during any of the other observation periods from Study Day –14 to Study Day 42. Animals in all treated groups (maximum of 9 of 12 in 5X group on Study Day 28) had skin flakes and off-white material at the application site, and four in the 5X group exhibited pruritus on Days 1, 2 or 3. No ocular, muscular, cardiovascular, or behavioral changes or abnormalities of the mucus membranes were observed in the treated cats. There were no morphological abnormalities in RBCs that could be attributed to treatment.

Overall, no treatment-related, biologically-significant effects on body weight, clinical biochemistry, or hematology, were reported...

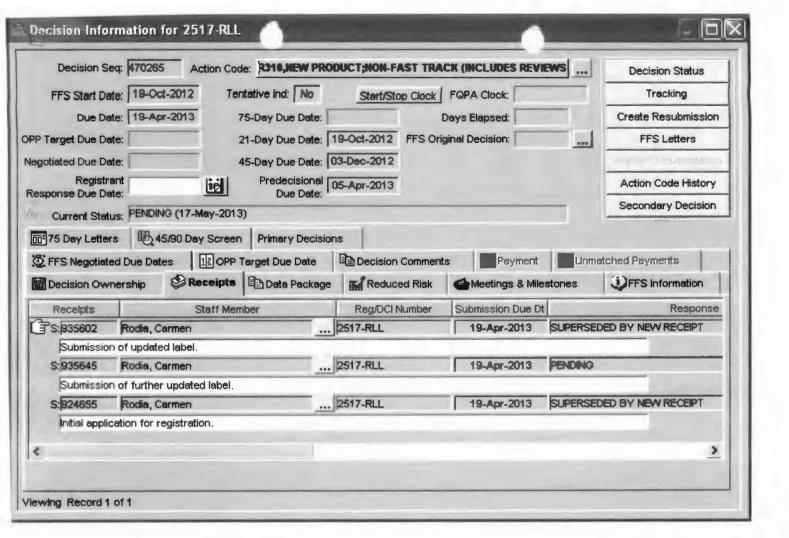
It is also noted that doses are not stated on the proposed label. HED concludes that the final dosages, as indicated on the label or as packaged in the applicator tubes, must be consistent with (no more than) the 1 X application rate in this study (0.5mL/kg). With this stipulation, and assuming that there are no additional adverse effects reported in the final report, the study is classified as **Acceptable/Guideline** for a companion animal safety study (OPPTS 870.7200) in cats (kittens).

- 11. Based on the study in MRID 44942009 TRB has concluded (memorandum dated December 5, 2012) that we can accept a 1.5 lb minimum kitten (or cat) body weight for a 9.7% fipronil product applied at 0.5 mL/(cat/kitten). Labeling for 2517-RLL should be revised to indicate a minimum kitten (or cat) body weight of 1.5 lbs.
- 12. The study in MRID 45618502 [Not 45615802, which is the citation in the data matrix] was reviewed (TXR 5005726, TRB review dated September 23, 2002) with the following comment for EPA Reg. No. 65331-4:

This study is classified as acceptable. The findings of this study are adequate to support the use of this registered product at the dosage rate of 0.5 mL/cat at 28-day intervals on breeding, pregnant and lactating female cats.

This citation supports the claim for 2517-RLL that: "Product can be used on breeding, pregnant, or lactating [cats] [female cats] [queens]."

13. The TRB Chemistry Team should review and accept the basic CSF (dated 09/28/2012) for 2517-RLL.



of Torget

eanti-1

Tension

Rodia, Carmen

From:

James Messina [jmessina@exponent.com]

Sent:

Thursday, May 16, 2013 3:31 PM

To:

Rodia, Carmen

Cc:

Gebken, Richard; Mary Hunt; Reginald Coler

Subject:

2517-RLL and 2517-RLA Revised Labels

Attachments:

2517-xxx Multi Dose Dog v13 1 5-16-13.docx; 2517-RLL Multi Dose Cat v13 1.docx

Dear Carmen,

Please find attached the revised labels. They were updated from earlier today based on a conversation with Richard.

Please let me know if you have any questions.

Best Regards,

James Messina
Principal Regulatory Consultant
Exponent
Center for Chemical Regulation and Food Safety
1150 Connecticut Avenue, N.W.
Suite 1100
Washington, DC 20036
202-772-4932
202-772-4979 fax
301-908-1181 cell

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Information in [] is optional.

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[Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels.]

Sergeant's Fipronil Multi-Dose for Cats

[ABNs:]

[Sergeant's® EctoadvanceTM Spot On for Cats]

[Sergeant's® EctoadvanceTM for Cats]

[Sentry® EctoadvanceTM Spot On for Cats]

[Sentry® EctoadvanceTM for Cats]

[Meridian® EctoadvanceTM Spot On for Cats]

[Meridian® EctoadvanceTM for Cats]

FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels. Not for residential use. Keep product in its original container. Do not repackage.

[For use ONLY on cats [[&] [and] kittens] over 1.5 lbs. and over 8 weeks of age] [Only for cats [[&] [and] kittens] over 8 weeks of age and over 1.5 lbs.]

[Ideal for shelter use when under direct supervision of veterinarian]

[Multi-dose bottle] [Multi-Dose Package]

[Convenient multi-dose bottle for in clinic use]

[Convenient multi-dose bottle for animal facility use]

[Accurate and convenient dosing for all sizes of cats]

[For use only by licensed veterinarians [on animals in their control or under their immediate supervision]

[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 14 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]

[Fleas]

[Kills adult fleas [for up to six weeks]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If cat is a high risk for flea reinfestation apply once a month]

[Kills fleas which may be a source of flea allergy dermatitis] [and] [flea bite anemia]]

[Ticks]

[Kills ticks including those that may transmit Lyme disease]

[Kills deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]

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Information in [] is optional.

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[Kills ticks [including][brown dog ticks] [(Rhipicephalus sanguineus)] [American dog ticks,] [(Dermacentor variabilis)] [and] [lone star ticks] [,][and] [deer ticks] [for up to [4 weeks] [1 month] [30 days]]]

[Multiple Infestations]

[Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old and older]

[Kills fleas, ticks, [mosquitoes] [&] [and] chewing lice]

[Monthly flea, tick, [mosquito] and chewing lice protection]

[Four] [4] [Three] [3] Way [Action] [Effectiveness] [Control] [kills fleas, [mosquitoes,] ticks, and chewing lice]

[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]

[[Four (4) Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]

[Once A Month Flea and Tick Treatment]

[Use [Brand Name] monthly to control ticks and chewing lice]

[Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]

[(**Brand Name**) provides convenient and effective flea, tick, chewing lice [and] [mosquito] control for cats and kittens over 8 weeks of age.]

[All Others]

[For Cats and Kittens 8 weeks of age or older]

[Can [use][apply] [on][to] kittens 8 weeks of age and older]

[Specially Formulated for Cats and Kittens Over 8 Weeks Old]

[Easy to Use [Application]]

[Apply monthly]

[Apply once every [4 weeks] [month] [30 days]!]

[Waterproof]

[Effective after bathing and exposure to water and sunlight]

[Can be used on breeding, pregnant and lactating [queens], [female] [cats]]

ACTIVE INGREDIENT:

Fipronil	9.70%
OTHER INGREDIENT[**]:	
TOTAL	100.00%

[**diethylene glycol monoethyl ether]

KEEP OUT OF REACH OF CHILDREN CAUTION

[See [Back] [Label] for Additional Precautionary Statements]

Net Contents:

[3.38 fl oz [(100 ml)]] [8.45 fl oz [(250 ml)]]

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON CATS AND KITTENS OVER 8 WEEKS OF AGE

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Information in [] is optional.

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[[Brand Name] for cats provides [[four] [three] [way] protection that kills fleas, ticks, [mosquitoes] and chewing lice. Kills deer ticks that may transmit Lyme disease. Kills brown dog ticks, American dog ticks, and lone star ticks. Prevents flea reinfestation for [[4][four] weeks] [[1] [one] month] [30 days].]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use on cats only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat a cat with more than one pesticide product at a time. Over dosing a cat can result in serious illness and even death. Use caution before using on medicated, debilitated, aged, pregnant, nursing cats, or cats with known organ dysfunction. If the cat is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

FIRST AID	
If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.
HOTLINE NUMBER	

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

16 May 2013 Revised Application Information in [1] is optional.

Version 13.1 Page 4 of 6 EPA No. 2517-RLL

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND THE CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on rabbits or animals other than cats. Do not allow your cat to ingest this product. Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 1.5 lbs. Do not over dose cat. Instruct the cat owner to separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

Side Effects: Instruct the owner to monitor the cat after application. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed the cat and continue to monitor the cat for the next 24 hours. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe the cat with a mild soap and rinse with large amounts of water. If signs persist or become more severe within a few days of application, immediately call 1-800-781-4738. If the cat has an unusual reaction to the initial application, evaluate the cat's condition before repeating application.

[CRP text found on top of cap: WHILE PUSHING DOWN TURN CLOSE TIGHTLY][Graphic may or may not appear anywhere on the label]



How to Apply

Weight/Application Amount		
Only for cats and kittens 8 weeks or older and over 1.5 lbs.		
Weight:	Apply:	
All sizes (weights)	(0.50 mL) or (0.50 cc)	

Application to be made using commercially available ≥1 mL (syringe must have 0.1 mL graduations), luer tip disposable syringe without needle. Use of non-sterile syringe is acceptable since applications are topical. Use syringe [(not included)] to measure and withdraw the appropriate amount of solution by inserting the syringe into the top of the bottle. Refer to table above for application rates. Part the cat's hair, and apply entire amount directly to the skin of the cat, as directed below. Do not apply more often than once every 4 weeks. When finished using product, replace the cap.

16 May 2013 Revised Application Information in [] is optional.

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EPA No. 2517-RLL

FREQUENCY OF APPLICATION

[Brand Name] [This product] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Keep product in its original container. Do not repackage. Store in a cool (below 77°F[/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

SYRINGE DISPOSAL: Do not reuse this syringe. Only discard empty syringes; do not discard syringes containing product. Discard disposable syringe in accordance with State and Local regulations.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738

[Coupon(s) inside or on outside of box]

Non-Emergency, call: 1-800-224-PETS (7387) [Made in USA]

Distributed by:

Sergeant's Pet Care Products, Inc.

Omaha, NE 68138-3710

[BAR CODE AREA][Lot code] EPA Reg. No. 2517-RLL

EPA Est. No. 2517-NE-1 [XXX-XX-XXX]

16 May 2013 Revised Application

Version 13.1

EPA No. 2517-RLL

Information in [] is optional.

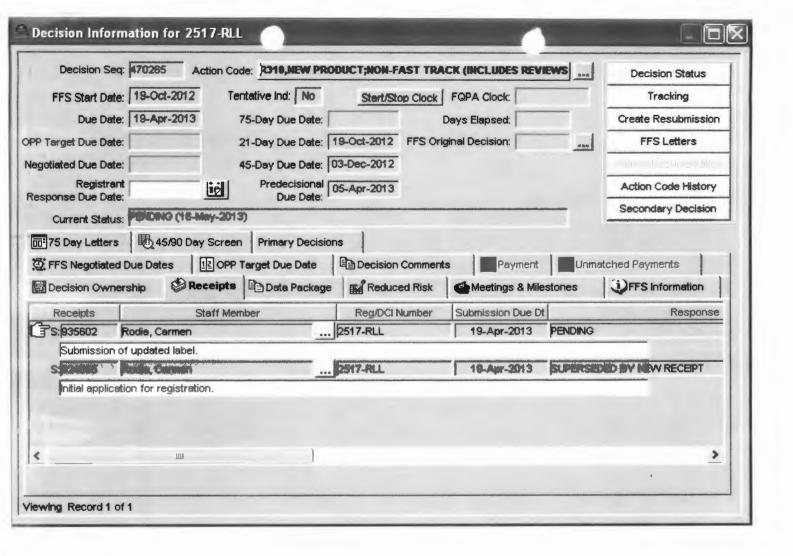
Page 6 of 6

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist

- [1] Read the label completely and follow directions
- [2] Weigh the cat
- [3] Do NOT use cat products on dogs
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals for 24 hours after treatment to avoid chance of ingestion
- [6] Not for residential use

[Optional graphics below may or may not appear anywhere on finished label]

April 1	Fleas	
To the	Adult Flea	
	Ticks	
	Deer Tick	
	Brown Dog Tick	
*	Lone Star Tick	
*	American Dog Tick	
*	Chewing Lice	
7	Mosquitoes	



- Target

Rodia, Carmen

From:

James Messina [jmessina@exponent.com]

Sent:

Thursday, May 16, 2013 1:08 PM

To:

Rodia, Carmen

Cc:

Gebken, Richard; Mary Hunt; Reginald Coler

Subject:

2517-RLL Label

Attachments:

2517-xxx Cat Multi Dose Lbl v13 1 5-16-13.docx

Dear Carmen,

Please find attached an updated label for the Sergeant's cat multidose product. Please review in support of the pending registration.

Best Regards,

James Messina
Principal Regulatory Consultant
Exponent
Center for Chemical Regulation and Food Safety
1150 Connecticut Avenue, N.W.
Suite 1100
Washington, DC 20036
202-772-4932
202-772-4979 fax
301-908-1181 cell

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Version 13.1

EPA No. 2517-RLL

Information in [] is optional.

Page 1 of 6

Optional text appears in brackets – the final product label may include some or all of the optional text on front, back, side or folded label panels.]

Sergeant's Fipronil Multi-Dose for Cats

[ABNs:]

[Sergeant's® EctoadvanceTM Spot On for Cats]

[Sergeant's® EctoadvanceTM for Cats]

[Sentry® EctoadvanceTM Spot On for Cats]

[Sentry® EctoadvanceTM for Cats]

[Meridian® EctoadvanceTM Spot On for Cats] [Meridian® EctoadvanceTM for Cats]

FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION

For use in veterinarian clinics, animal shelters, grooming facilities and boarding kennels. Not for residential use. Keep product in its original container. Do not repackage.

[For use ONLY on cats [[&] [and] kittens] over 2 lbs. and over 8 weeks of age] [Only for cats [[&] [and] kittens] over 8 weeks of age and over 2 lbs.]

[Ideal for shelter use when under direct supervision of veterinarian]

[Multi-dose bottle] [Multi-Dose Package]

[Convenient multi-dose bottle for in clinic use]

[Convenient multi-dose bottle for animal facility use]

[Accurate and convenient dosing for all sizes of cats]

[For use only by licensed veterinarians [on animals in their control or under their immediate supervision]

[Mosquitoes]

[Kills mosquitoes] [within 24 hours for up to 14 days] [and within 48 hours for up to 28 days]

[Chewing Lice]

[Kills chewing lice]

[Fleas]

[Kills adult fleas [for up to six weeks]]

[Kills Fleas Up to [4 weeks] [1 month] [30 days]!]

[If cat is a high risk for flea reinfestation apply once a month]

[Kills fleas which may be a source of flea allergy dermatitis] [and] [flea bite anemia]]

[Ticks]

[Kills ticks including those that may transmit Lyme disease]

[Kills deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]

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Information in [] is optional.

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[Kills ticks [including][brown dog ticks] [(Rhipicephalus sanguineus)] [American dog ticks,] [(Dermacentor variabilis)] [and] [lone star ticks] [,][and] [deer ticks] [for up to [4 weeks] [1 month] [30 days]]]

[Multiple Infestations]

[Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old and older]

[Kills fleas, ticks, [mosquitoes] [&] [and] chewing lice]

[Monthly flea, tick, [mosquito] and chewing lice protection]

[Four] [4] [Three] [3] Way [Action] [Effectiveness] [Control] [kills fleas, [mosquitoes,] ticks, and chewing lice]

[[4 week] [1 month] [30 day] Flea [and] [&] Tick [Application] [Treatment]!]

[[Four (4) Week] [1 month] [Flea, Tick, [Mosquito] and Chewing Lice Control]

[Once A Month Flea and Tick Treatment]

[Use [Brand Name] monthly to control ticks and chewing lice]

[Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]

[(**Brand Name**) provides convenient and effective flea, tick, chewing lice [and] [mosquito] control for cats and kittens over 8 weeks of age.]

[All Others]

[For Cats and Kittens 8 weeks of age or older]

[Can [use][apply] [on][to] kittens 8 weeks of age and older]

[Specially Formulated for Cats and Kittens Over 8 Weeks Old]

[Easy to Use [Application]]

[Apply monthly]

[Apply once every [4 weeks] [month] [30 days]!]

[Waterproof]

[Effective after bathing and exposure to water and sunlight]

[Can be used on breeding, pregnant and lactating [queens], [female] [cats]]

[Fipronil (9.7%)]

[[Brand Name] Contains fipronil, same active ingredient used in [FRONTLINE®] [Company name] brand products.*]

[[Brand Name] [products] contain fipronil, same active ingredient used in [FRONTLINE®]

[Company name] brand products.*]

[[*] This product is not manufactured or distributed by [Merial®] [Company name], the makers of [FRONTLINE®][Brand name][brand products]]

[[Brand Name] is a trademark of [Company Name]]

ACTIVE INGREDIENT:

Fipronil	9.70%
OTHER INGREDIENT[**]:	
TOTAL	100.00%

[**diethylene glycol monoethyl ether]

KEEP OUT OF REACH OF CHILDREN CAUTION

16 May 2013 Revised Application Information in [] is optional.

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EPA No. 2517-RLL

[See [Back] [Label] for Additional Precautionary Statements]

Net Contents:

[3.38 fl oz [(100 ml)]] [8.45 fl oz [(250 ml)]]

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON CATS AND KITTENS OVER 8 WEEKS OF AGE

[[Brand Name] for cats provides [[four] [three] [way] protection that kills fleas, ticks, [mosquitoes] and chewing lice. Kills deer ticks that may transmit Lyme disease. Kills brown dog ticks, American dog ticks, and lone star ticks. Prevents flea reinfestation for [[4][four] weeks] [[1] [one] month] [30 days].]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS.

For external use on cats only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat a cat with more than one pesticide product at a time. Over dosing a cat can result in serious illness and even death. Use caution before using on medicated, debilitated, aged, pregnant, nursing cats, or cats with known organ dysfunction. If the cat is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product.

	FIRST AID				
If swallowed:	Call a poison control center or a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.				
If in eyes:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.				
If on skin:	Wash with plenty of soap and water. Get medical attention if irritation persists.				
HOTLINE NUMBER					

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-781-4738 for emergency medical treatment information.

16 May 2013 Revised Application Information in [] is optional.

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EPA No. 2517-RLL

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. FOR USE ONLY BY LICENSED VETERINARIANS ON ANIMALS IN THEIR CONTROL OR UNDER THEIR IMMEDIATE SUPERVISION. DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND THE CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not use on rabbits or animals other than cats. Do not allow your cat to ingest this product. Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than 2 lbs. Do not over dose cat. Instruct the cat owner to separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.

Side Effects: Instruct the owner to monitor the cat after application. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed the cat and continue to monitor the cat for the next 24 hours. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe the cat with a mild soap and rinse with large amounts of water. If signs persist or become more severe within a few days of application, immediately call 1-800-781-4738. If the cat has an unusual reaction to the initial application, evaluate the cat's condition before repeating application.

[CRP text found on top of cap: WHILE PUSHING DOWN TURN CLOSE TIGHTLY][Graphic may or may not appear anywhere on the label]



How to Apply

Weight/Application Amount						
Only for cats and kittens 8 weeks or older and over 2 lbs.						
Weight: Apply:						
All sizes (weights)	[0.50 mL] [0.50 cc] [0.017 fl					
	oz]					

Application to be made using commercially available >1 mL (syringe must have 0.1 mL graduations), luer tip disposable syringe without needle. Use of non-sterile syringe is acceptable since applications are topical. Use syringe [(not included)] to measure and withdraw the appropriate amount of solution by inserting the syringe into the top of the bottle. Refer to table above for application rates. Part the cat's hair, and apply entire amount directly to the skin of the cat, as directed below. Do not apply more often than once every 4 weeks. When finished using

16 May 2013 Revised Application Information in [] is optional.

Version 13.1 Page 5 of 6

EPA No. 2517-RLL

product, replace the cap.

FREQUENCY OF APPLICATION

[Brand Name] [This product] remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for [30 days] [4 weeks].

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Keep product in its original container. Do not repackage. Store in a cool (below 77°F[/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

SYRINGE DISPOSAL: Do not reuse this syringe. Only discard empty syringes; do not discard syringes containing product. Discard disposable syringe in accordance with State and Local regulations.

CONTAINER DISPOSAL: If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[WARRANTY Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Sergeant's is committed to providing high quality products. To the extent consistent with applicable law, Sergeant's makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, Sergeant's, the manufacturer, or the Seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[If you have questions or comments about this product, please write: [Sergeant's] [SENTRY] Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.]

In Case of Emergency, call: 1-800-781-4738 Non-Emergency, call: 1-800-224-PETS (7387) [Coupon(s) inside or on outside of box]

[Made in USA]

Distributed by:

Sergeant's Pet Care Products, Inc.

Omaha, NE 68138-3710

[BAR CODE AREA][Lot code] EPA Reg. No. 2517-RLL

EPA Est. No. 2517-NE-1 [XXX-XX-XXX]

16 May 2013 Revised Application Information in [] is optional.

Version 13.1

Page 6 of 6

EPA No. 2517-RLL

[Look at the Label (Look at the Label icon) [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical] Checklist

- [1] Read the label completely and follow directions
- [2] Weigh the cat
- [3] Do NOT use cat products on dogs
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals for 24 hours after treatment to avoid chance of ingestion
- [6] Not for residential use

[Optional graphics below may or may not appear anywhere on finished label]

Total	Fleas	
1100	Adult Flea	
	Ticks	
	Deer Tick	
The state of the s	Brown Dog Tick	
*	Lone Star Tick	
*	American Dog Tick	
*	Chewing Lice	
	Mosquitoes	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLEUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DECISION No.: 470265

Bruce 7. Kuthers C8 apr 2013 8Rv 4/9/13

DP BARCODE No.: D407773 FILE SYMBOL NO.: 2517-RLL

PC CODE: 129121 ACTION CODE: R 310

FOOD USE: NO PRODUCT NAME: Sergeant's Fipronil Multi Dose for Cats

DATE OUT: April 08, 2013

SUBJECT: End Use Product Chemistry Review

Product Name: Sergeants Fipronil Multidose for Cats

FROM: Bruce F. Kitchens, Chemist

Product Chemistry Team

Technical Review Branch/RD (7505P)

TO: RM 10. Richard Gebken/Driss Benmhend

Insecticide Branch/RD (7505P)

INTRODUCTION:

The registrant, Sergeant's Pet Care Products, Incorporated, is submitting an application to register the proposed end-use product, Sergeant's Fipronil Multi Dose for Cats. The active ingredient in this product is Fipronil () at a label nominal concentration of 9.7% a.i. This product is intended for use as a spot on treatment for cats. In support of this request, the registrant is submitting proposed basic and alternate (1&2) Confidential Statements of Formula (CSF) dated 28 Sept 2012, a draft label and product chemistry data contained in MRID Numbers 480595-01 and 480595-02. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Fipronil (9.70% ai)

Formulation Type: Spot-On (Liquid)

2. Has the registrant claimed substantial similarity to a registered product?

[] Yes; [X] No

- 3. All of the source materials of the active ingredient are derived from registered sources- [X] Yes [] No
- 4. All inert ingredients have been screened by IIAB and are approved for the proposed labeled uses.

PC CODE: 129121 **ACTION CODE: R 310** FOOD USE: NO PRODUCT NAME: Sergeant's Fipronil Multi Dose for Cats 5. Confidential Statement of Formula: [X] Basic - Dated - Dated: 28 Sept 2012 Resubmitted Dated: [X] Alternate (1&2) - Dated: 28 Sept 2012 Resubmitted Dated: Product label a. Ingredient statement: Nominal concentration of Al listed on CSF concurs with product label (PR Notice 91-2). [X] Yes, if not, explain below: Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient) [X] Yes; [] No; if not, explain below Metallic equivalent: [] Yes [X] NA Soluble arsenic: [] Yes [X] NA [] Yes [X] NA Isomeric ratios: Acid Equivalent: [] Yes [X] NA b. Health related sub statements: Product contains? Petroleum distillate at > 10%: [] Yes; [] No; [X] NA Methanol at > 4%: [] Yes: [] No: [X] NA Sodium nitrate/sodium nitrite [] Yes; [] No; [X] NA c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown? [] Yes [X] No Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)? [] Yes; [] No; [X] NA; if not, explain below d. Label requires an additional Storage and Disposal statement: [] Yes [X] No; if yes explain below:

FILE SYMBOL NO.: 2517-RLL

DECISION No.: 470265

DP BARCODE No.: D407773

6.

DP BARCODE No.: D407773 FILE SYMBOL NO.: 2517-RLL DECISION No.: 470265

PC CODE: 129121 ACTION CODE: R 310

FOOD USE: NO PRODUCT NAME: Sergeant's Fipronil Multi Dose for Cats

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment	MRID Nos.
			Yes No		of Data	
830.1550	Product Ider	ntity & Composition	X		А	480595-01
830.1600	Description of produce the	of materials used to product	Х		А	480595-01
830.1650	process	of formulation	Х		A	480595-01
830.1670	Discussion of impurities	on the formation of	Х		А	480595-01
830.1700	Preliminary analysis			X	N/A	
		Standard certified limits	Х		A	
	Certified limits	Proposed Limits				
830.1750	(158.350)	Justification for wider limits				see basic csf 9/28/13
830.1800	Enforcemen	t analytical method	X		А	481226-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

DP BARCODE No.: D407773 FILE SYMBOL NO.: 2517-RLL DECISION No.: 470265

PC CODE: 129121 ACTION CODE: R 310

FOOD USE: NO PRODUCT NAME: Sergeant's Fipronil Multi Dose for Cats

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's MRID Nos Assessment of Data	
830.6303	Physical State	Clear, yellow liquid (Gardner 1-2) liquid with a faint pleasant odor	А	480595-02
830.6315	Flammability	Flashpoint >90°C	А	480595-02
830.6316	Explodability	Product does contain explosive components	N/A	
830.7000	рН	Product is insoluble in water	N/A	
830.7300	Density (units)	1.01 – 1.05 g/ml	A	480595-02

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

DP BARCODE No.: D407773 FILE SYMBOL NO.: 2517-RLL DECISION No.: 470265

PC CODE: 129121 ACTION CODE: R 310

FOOD USE: NO PRODUCT NAME: Sergeant's Fipronil Multi Dose for Cats

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed end-use product and has concluded that:

1. The basic formula CSF for the proposed end-use product, Sergeant's Fipronil Multi Dose for Cats dated 28 Sept 2012 is acceptable.

The proposed alternate formulas for the end-use product, Sergeant's Fipronil Multi Dose for Cats dated 28 Sept 2012 are acceptable.

- 2. This submission satisfies the data requirements as specified in 40 CFR 158.320, 158.325, 158.335, 158.340, 158.350, and 158.355 with respect to product identity and composition, description of materials used to produce the product, description of formulation process, discussion of formation of impurities, certified limits, and enforcement analytical method.
- 3. This submission satisfies the data requirements as specified in 40 CFR 158.310 with respect to physical and chemical properties except for storage stability and corrosion characteristics. The registrant states that studies are in progress and will be submitted to Agency upon completion for review.
- 4. This product meets the criteria specified in 40 CFR 152.43 with respect to alternate formulations.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

CHILD-RESISTANT PACKAGING REVIEW Technical Review Branch

IN 12/20/2012 OUT 3/7/2013 Posselind J. Gross
RD, TRB, Reviewed by Rosalind L. Gross 3/7/2013
EPA Reg. No. or File Symbol <u>2517-RLL</u>
DP Barcode DP407788
Decision # 470265 EPA Petition or EUP No
Date Division Received 9/28/2012
Type Product(s) Insecticide (flea product)
Data Accession No(s). 48957901 (GLM29218) 48957902 (GLM29275)
Product Mgr./Chemical Review Mgr/Contact Person RM 10 Richard Gebken Division RD
Product Name(s) Sergeant's Fipronil Multi Dose for Cats
Company Name(s) Sergeant's Pet Care Products, Inc.
Submission Purpose Review of CRP studies to determine if they are adequate to support CRP certification for this product
Active Ingredient(s), PC code, & % Fipronil 9.7%

Summary of Findings

In conclusion all the requirements for CRP have been met for EPA Registration No. 2517-RLL. For details see Analysis of Data and Conclusions section below.

Should any human experience/epidemiological evidence indicate a

problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

Package

The package is a 3.38 fluid ounce (100ml) or 8.45 fluid ounce (250ml) bottle with either a 28mm or 24mm Berry Plastics Corporation CR4 closure (previously known as the FG Series closure by Rexam Healthcare). The Berry Plastics Corporation CR4 closure is an ASTM Type IA closure. This is a two piece plastic/plastic continuously threaded closure. The closure is opened by pushing down on the closure and simultaneously turning it counterclockwise. The manufacturer's instructions on the closure are:



Toxicity

The toxicity of the product is based on the toxicity of Fipronil. The toxic or harmful amount of Fipronil for an 11.4 kg child is 2.5mg/kg times 11.4kg, which equals 28.5mg. Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1020mg/ml x 0.097 Fipronil] = 0.288 ml = **0.29 ml for Fipronil** EPA REG No. 2517-RLL.

Failure

For the purposes of CRP testing **a child failure** is opening the package or gaining access to any amount of its contents.

A Senior Adult Use Effectiveness failure is failure to open the package in the prescribed test time of 5 minutes or a failure to open or properly resecure the package in the prescribed test time of 1 minute for the second package.

Analysis of Data and Conclusion

The CRP certification submitted September 28, 2012 for EPA Registration No. 2517-RLL is acceptable. The label submitted September 28, 2012 for EPA Registration

No. 2517-RLL is acceptable.

A **comprehensive** review was done for the child-resistant effectiveness, CRE, and Senior Adult Use Effectiveness, SAUE, for the 28mm CR4 closure (MRID 48957901 (GLM29218)) and the 24mm CR4 closure (MRID 48957902 (GLM29275)). In both instances the child study served as the CRE study and as the Senior Resecuring study.

Child Study 28mm CR4 closure (MRID 48957901 (GLM29218)) involved giving 100 children the packages, which appeared to be resecured properly, from the 1 minute SAUE. The children were given ten minutes to open the package with a demonstration at the five minute mark per 16 CFR 1700.20. A child failure was defined as opening the package or gaining access to any amount of its contents. There were 7 child failures. Three of the child failures were before the demonstration and there were 7 failures for the full 10 minute test. This study was a pass according to the child sequential test in 16 CFR 1700.20.

Senior Adult Use Effectiveness Study 28mm CR4 closure (MRID 48957901 (GLM29218)) involved having the test subjects open the test package during a 5 minute test period and open and properly resecure a second test package in a 1 minute test period. The results were 100% SAUE, and these results were not affected by any child resecuring failures. The study is a pass of the Senior Adult test in 16 CFR 1700.20 and the effectiveness specifications in 16 CFR 1700.15(b).

Child Study 24mm CR4 closure (MRID 48957902 (GLM29275)) involved giving 98 children the packages, which appeared to be resecured properly, from the 1 minute SAUE. The children were given ten minutes to open the package with a demonstration at the five minute mark per 16 CFR 1700.20. A child failure was defined as opening the package or gaining access to any amount of its contents. There were 4 child failures. One of the child failures was before the demonstration and there were 4 failures for the full 10 minute test. The child age distribution was not fully in accord with the regulations in 16 CFR 1700.20. The 45-48 month old age group had 41 children, which exceeds the 40% distribution required for that age group. Additionally, there was one female child who was not assigned to any age group. The extra child in the 45-48 month old age group and the one female child not assigned to any age group should have been replaced. However, these errors did not affect the results because even if these two children were replaced in a worst case scenario the study was still a pass. This study was a pass according to the child sequential test in 16 CFR 1700.20.

Senior Adult Use Effectiveness Study 24mm CR4 closure (MRID 48957902 (GLM29275)) involved having the test subjects open the test package during a 5 minute test period and open and properly resecure a second test package in a 1 minute test period. The results were 98% SAUE, and these results were not affected by any child resecuring failures. The study is a pass of the Senior Adult test in 16 CFR

1700.20 and the effectiveness specifications in 16 CFR 1700.15(b).

In conclusion all the requirements for CRP have been met for EPA Registration No. 2517-RLL.

Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM:

From: Kevin Sweeney, Senior Entomologist

Date: April 3, 2013

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 407790 Decision no.: 470265 Submission no: 924655 Action code: R310

Product Name: Sergeant's Fipronil Multi-dose for Cats

EPA Reg. No or File Symbol: 2517-RLL

Formulation Type: RTU spot-on with multi-use applicator

Ingredients statement from the label with PC codes included: 9.7% fipronil (pc code:

129121)

Application rate(s) of product: prescribed volumes are applied. The amount applied to an

animal is dependent upon animal weight.

Use pattern: cat spot-on product OCSPP Guidelines: 810.3300

I. Action Requested: Review cited studies and new label. A similar product was not cited.

II. Background: This is new cat spot-on products with the adulticide component consisting of 9.7% fipronil. The registrant cited Merial's database for fipronil only as an adulticide.

III. Cited studies:

All study citations are for fipronil efficacy data on cats.

Fipronil only
46019202
43121119
43121120
43121121
43577713
45628101
45628102
45628103

Fipronil dose calculations:

Fipronil is applied at the same rate as Frontline products -0.5 ml per cat of any weight. This application has been shown to be efficacious against ectoparasites of cats listed on the label.

IV. ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

- 1. The product label is acceptable provided the registrant makes the following changes:
- a. Remove all ticks and tick related claims. Data were not cited for ticks. Data do exist for ticks but the data matrix needs updating.
- b. The registrant references a product with 9.7% fipronil that is applied to cats where EPA has accepted the following claims. Otherwise, the claims should be removed.
 - [Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]
- c. Note that this product is 9.7% fipronil while the other Sergeant's products have 9.8% fipronil that have these claims (EPA reg. No. 2517-134 and 146). The difference in the fipronil application rate is likely to be negligible.
- 2. The PM should also pay attention to claims that reference other products in order to: "maximize the power", and "provide year-round protection".

PRIA 2 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only)

21 D Expe Divi	Pay Screen Start Date:	2/12 Date	Fee 1	Paid: Y	es 🗾	
EPA	Reg. Number: 25/7-RLL EPA Receipt Date: 09	1/28/	1/2			
	Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & coincluding package type	omplete		X		
2	Confidential Statement of Formula all boxes completed, form s dated (EPA Form 8570-4) (Link to form)	igned, a	nd	X		
2	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no	0-1		
3	Certification with Respect to Citation of Data (EPA Form 8570 form) completed and signed (N/A if 100% repack))-34) (L	ink to	X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use or	nly.				
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link completed and signed (N/A if source is unregistered or applicant of technical)	to form		X		
	Data Matrix (EPA Form 8570-35) (Link to form) both internal ar copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if repack)		nal	X		
5	a) Selective Method (Fee category experts use)	yes	no	-		
	b) Cite-All (Fee category experts use)	/~				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labelin (Electronic labels on CD are encouraged and guidance is avail http://www.epa.gov/pesticides/regulating/registering/submissions/index.line)	able)(li	nk to	X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X	
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)	,	X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)		X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C. a) List study (or studies) not included with application		

Comments:



Inerts Approved for Non-Food Use

Jacket Pass

Fa

418110 4129579

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Pages 64-74 - *Claimed confidential by submitter*

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI). Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline	Group A: Product Chemistry Data	EP Data Submitted		MP Data Submitted		TGAI	
No.	Study Title	Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	X					
830.1600	Description of materials used to produce the product	Χ.					
830.1650	Description of formulation process	X					
830.1670	Discussion on the formation of impurities	X					
830.1700	Preliminary analysis	X					
830.1750	Certified limits (158.345)	X					
830.1800	Enforcement analytical method	X					

Guideline	Group B: Product Chemistry Data Study	EP Data Submitted		MP Data Submitted		TGAI	
No.	Title	Yes	No	Yes	No	Yes	No
830.6302	Color	X					
830.6303	Physical State	×					
830.6304	Odor	X					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	X					
830.6315	Flammability	X			<u> </u>		
830.6316	Explodability	×					
830.6317	Storage stability	X					
830.6319	Miscibility	X					
830.6320	Corrosion Characteristics	X					
830.6321	Dielectric Breakdown Voltage	Ĺ <u></u>	1				
830.7000	рН		X				
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	X					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	$\perp \times$					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

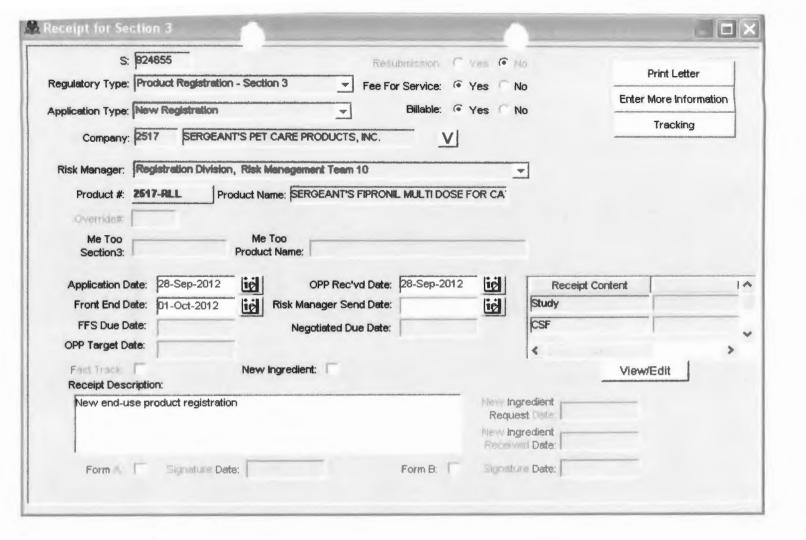
R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline	Acute toxicity (6 pack)	Data submitted		Cited	
No.			No	Yes	No
870.1100	Acute Oral (LD50)			X	
870.1200	Acute Dermal (LD50)			X	
870.1300	Acute Inhalation (LC50)			X	
870.2400	Acute Eye Irritation	_		λ	
870.2500	Acute Dermal Irritation			X	
870.2600	Dermal Sensitization			X	

Efficacy - which guideline is used depends on the proposed label use

Guideline		Data submitted		Cited		
No.	Study Title	Yes	No	Yes	No	Comments
810.3100	Soil Treatments for Imported Fire Ants					
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets			X		
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					



Page 78 - *Claimed confidential by submitter*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

October 2, 2012

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP Decision Number: D-470265

EPA File Symbol or Registration Number: 2517-RLL

Product Name: SERGEANT'S FIPRONIL MULTI DOSE FOR CATS

EPA Receipt Date: 28-Sep-2012 EPA Company Number: 2517

Company Name: SERGEANT'S PET CARE PRODUCTS, INC.

KELLY R. HOSKINS SERGEANT'S PET CARE PRODUCTS, INC. 10077 SOUTH 134TH STREET OMAHA, NE 68138-3710

SUBJECT: Receipt of Application and 50% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 50% small business waiver request, and cerification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310 NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

n De

Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

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This package includes the following	for Division			
 New Registration Amendment Studies? Fee Waiver? volpay Reduction: 	○ AD ○ BPPD ○ RD Risk Mgr. 10			
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	924655 2517-RLL 9/28/2012			
This item is NOT subject to	o FFS action.			
Action Code: Requested: 2310 Granted: 2310 Amount Due: \$ 4807.00	Parent/Child Decisions:			
Reviewer: Remarks:	Uncleared Inert in Product Date: 10/24/2			

Pages 81-87 - *Claimed confidential by submitter*

Pages 88-90 - *Confidential Statements of Formula may be entitled to confidential treatment*